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| 10/829,506 | 04/22/2004 | Marvin John Cervantes | P1482 US (2650/81) | 7331 |

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| EXAMINER |
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RYCKMAN, MELISSA K

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02/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/829,506 | Applicant(s) CERVANTES, MARVIN JOHN | |
| | Examiner MELISSA RYCKMAN | Art Unit 3773 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/22/04 has been entered.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "10 and 20" have been used to designate the sleeve in Fig. 1. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: there is no reference sign for the o-ring. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

Claims 1 and 5-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed application does not teach where the o-ring is disposed in relation to the port, specifically "the o-ring disposed at a distal end of the port".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 5-9 recites the limitation "the stent deployment assembly" in the seventh line of claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,5,7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al. (U.S. Patent No. 6,270,521).

Claim 1:

Fischell teaches a system for treating a vascular condition, comprising: a catheter (12); a stent assembly (40) coupled to the catheter; the stent assembly comprising a coated stent including a stent framework and a drug coating disposed on at least a portion of the stent framework (col. 5, ll. 32-34); a protective sleeve (34) removably covering the stent deployment assembly and at least a portion of the catheter, wherein said sleeve comprises a hollow tube having a proximal outer diameter, a medial inner diameter, and a distal inner diameter (fig. 2b); and wherein the distal inner diameter is sufficient to encircle an outer diameter of the stent deployment assembly (fig. 2b), and wherein the medial inner diameter is sufficient to encircle an

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outer diameter of the catheter, and wherein the distal inner diameter is open (fig. 2b), wherein the protective sleeve is removed from covering the stent (fig. 2c) framework prior to deploying the stent (capable of being used as described), and a port to a vessel (18), the port including an o-ring having an o-ring inner diameter (portion of 18 acts as an o-ring), the o-ring disposed at a distal end of the port (part of element 18 is at the distal end of the port) wherein a proximal portion of the sleeve (34) is positioned proximal to the o-ring and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter (Fig. 2c).

Claim 5:

Fischell teaches the sleeve comprises a material selected from the group consisting of nylon, polyurethane, polyethylene terephthalate, polyethylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, an elastane, a thermoplastic elastomer, a woven polymeric fabric, or an expandable polymeric sheet (nylon, col. 2, ll. 50-52).

Claims 7 and 8:

Fischell teaches a lubricious coating on at least a portion of a surface of the sleeve (col. 2, ll. 54), the examiner interprets the coating to be a lubricious film.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (U.S. Patent No. 6,270,521) as applied to claim 1 above.

Claim 6:

Fischell teaches the invention as claimed above, however does not specify the sleeve comprising a material that dissolves while in a vasculature. It would have been obvious to one of ordinary skill in the art to use a biodegradable material as it is well known in the art to use a biodegradable material for a stent sleeve, as this omits a surgery to remove the sleeve later on.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (U.S. Patent No. 6,270,521) as applied to claim 1 above, and further in view of Roberts et al. (U.S. Patent No. 5,984,964).

Fischell teaches the claimed invention above, however does not specify dimensions of the sleeve, however Roberts teaches the sleeve has a distal inner diameter of substantially .071 centimeters, a distal outer diameter of substantially .0825 centimeters (col. 4, ll. 52-59), a medial inner diameter (L7) of .045 centimeters, and a medial outer diameter of .055 centimeters (col. 4, ll. 59-63).

It would have been obvious to one of ordinary skill in the art to have the dimensions of Roberts as these dimensions are appropriate for use in the vasculature.

Response to Arguments

Applicant's arguments filed 10/13/08 have been fully considered but they are not persuasive. The applicant generally argues the newly amended claims overcome the prior rejection. The examiner's position is the newly amended claims were not present at the original filing of the application, as described above, and element 18 of Fischell which can act as an o-ring, has a portion disposed at a distal end of the port. The examiner also notes that the applicant must include structure regarding "the protective sleeve is removed from covering the stent framework prior to deploying the stent" because many stent deployment systems including Fischell are capable of being used as described.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

/Melissa Ryckman/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773